Claim Rejections:

The newly added and amended claims eliminate the objections made by the Examiner by the applicant specifically limiting claims so that the claims distinguish over the references cited. Specifically the claims eliminate the use or need of a plunger or penetrating shaft as required by the prior art of Guirguis. In addition, the claims described as cited in the specification that depressing the activation means does not require the adjustment of a lid or use of a cap, plungers, plenums, and tilting of the said container means.

As cited in last Office Action dated 07/27/04 page 4 in which the Examiner clearly states that the Guriguis device **requires** the lid to be sealed activating the fluid releasing element. No such requirement is needed or desired by the present art in fact that and many other reasons are why this device is a marked advancement in the art. See the present art of Smith's specification pages 5-7. Without the cap being screwed on the device of Guriguis the **device will not work**. Try to understand, if a collector collects urine they want to close the device to prevent spillage but not necessarily read the assay or activate it. The cup could be given to a donor who urinates into the cup and then caps it. The assay will activate and the results will be shown to the donor, which could cause multiple problems, believe me, the analyst do not want the donors to observe the results of the test or be responsible for activation of the assay. With the present art the donor could urinate into the device, place a cap on it or not and hand it back to the collector/analyst. When the collector/analyst had time they will activate the device when they are ready for analysis. Again, this is a **marked** advancement in the art not capable by the prior art. No such limitation exists with the present art. Which is a method using a cup that has a shaft that is inherently dangerous to the user and non-dysfunctional unlike the present art. The device links the cap and the plunger in together requiring more than one step to just activate the device if possible. The device of Guirguis in no way physical,

operationally, or otherwise resembles the device of the present art and even if one could apply the art of Guirguis a completely different cup design there would be no way to take the prior art of Guirguis and create the present and novel art of Smith and Lanier. This places the application in condition for allowance.

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the new claims 6 and 10 all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

The Claims Rejection Under 35 USC § 102

The new claims 6-10 have overcome the Examiners rejections based on the claims of 1 and 5 under 35 U.S.C. 102(e) as being anticipated by Guirguis . This reference describes a method for the collecting and testing fluid using a plunger (spike) that is dangerous to the user (donor) and recipient (lab tech) much less the plastic would probably shatter upon first causing a bio-hazard as the specimen would no longer be contained by the prior art device of Guirguis. The antiquated technology of Guirguis is many years old and was never implemented because it does not work and has nothing to do with the present art of a method for the diagnostics determination of analytes of interest using a cup that requires no plunger, spikes, interaction with the lid, etc. The Guirguis has no similar reference even remotely resembling the present art. The attempt to use an ancient prior art that lacks implementation is a strained interpretation of the present art and has no relative bearing. The applicant would urge the examiner to use any of the examples as taught in the present specification and find the same example in any of Guirguis specification. The current device does not use a spike or have need for this limitation and this limitation is used in the claims of the present art. The present art does not use a lid as a prerequisite or a plunger (spike) and demonstrates distinct physical features that clears any § 102 rejections with reference to Guirguis. In fact, wherein the art of Smith's depressing the activation means does not require the adjustment of a lid or use of a cap, plungers, plenums, and tilting of the said container means. Guirguis device requires the use of a first chamber, a third chamber, a releasing element (plunger/spike), a lid with teeth with one-way rotation. It goes on and on. The Smith and Lanier patent has no such **limitations**. The physical features of Smith are completely different (**novel**) from that of Guirguis clearing the claims of Smith from any §102 rejections. This is patentably distinct and "novel" in structure and functionality over the Guirguis device. Because of this and other reasons the Smith and Lanier device is not limited to all of the requirements of the Guirguis device.

Again, any rejection to canceled claims 1and 5 in view of new claims 6-10 as being anticipated by Guirguis under 35 U.S.C. § 102 should be overcome because Guriguis does not teach applicant's limitations as claimed, i.e., without the use of a

plunger, tilting, plenums, etc., as required by Guirguis. The cup of Smith and Lanier when depressing the activation means does not require the adjustment of a lid or use of a cap, plungers, plenums, and tilting of the said container means.

Therefore, Guirguis fails the first step of inquiry with respect to a **35 U.S.C. § 102** rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." The device of Smith and Lanier uses a "**new principle of operation**" in that include the use of a device with a activation means that does not spike / plunger though plastic to activate (endangering lives) to perform assays for analytes of interest. Never taught by Guirguis or any other prior art. The applicant's invention solves a different problem than the reference, and such differences are cited in the new and amended claims, such as no requirement for a spike, tilting, etc.. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35 U.S.C. 102, and because the invention of Smith and Lanier recites numerous novel physical features that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102 should be reversed.

Again, rejection to new claims 6-10 as being anticipated by Guirguis under 35 U.S.C. § 102 are not patentably defensible and therefore the new claims should be allowed because Guirguis does not teach applicant's limitations as claimed and therefore, Guirguis fails the first step of inquiry with respect to a **35 U.S.C. § 102** rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the

claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it."

As the Appellant and other courts have cited, hindsight view of prior art is not allowable. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in re Fritch supra, 1784.

Thus the applicant submits that the present invention clearly recites novel physical subject matter which distinguishes over any possible use of Guirguis.

The Novel Physical features of Claims 6 - 10 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 102.

It is impermissible to use hindsight reconstruction of an invention to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... "Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or `template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that `[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a ***prima facie*** case of the obviousness, it is necessary for the examiner to present ***evidence***, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art ***would have been led*** to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can ***reconstruct*** and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a ***prima facie*** case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the ***motivating force*** which would impel one skilled in the art to do what the ***applicant has done."***

The Novel Physical Features Of New Claims 6-10 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The References Under § 102.

Conclusion

The applicant disagrees with the Examiners rejection of deleted claims of the Office Action dated 07/27/04. The lid the applicant's invention is not equivalent to Guirguis by any stretch of the imagination. The following table is self-explanatory. How can the devices be equivalent if ones if required to activate the device the does not require it?

The Components:	**Smith/Lanier**	**Guirguis**
Lid (Cap) Activates the Device	NO	YES
Lid Closes the Container	YES	YES
Lid is Reqiured for Activation	NO	YES
Lid is Required at all	NO	YES
Tilting of the Device required	NO	YES
Plunger Required	NO	YES
Plenums Required	NO	YES

The applicant makes not claims to requirement for the lid to activate, In fact, the applicant cites this in this response page 7 and the specification pages 5, 6, etc., of the application. From page 6 of the specification "It has been found that the foregoing objects of the present art are accomplished in accordance with this invention by providing a collection and analyzing cup that is designed to collect the specimen and immediately have the lid secured onto the top of the cup. **Then the user can analyze the specimen when ready**." The last sentence has nothing to do with the activation of the cup. In fact in the specification pages 5-7 it is clearly defined that there is no adjustment of a lid or use of a cap, plungers, plenums, and tilting of the said container means.

For all of the above reasons, applicant submits that the specification and claims are now in proper form, and that the claims all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,

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Certificate of Mailing

I certify that on the date below I have mailed the above response to the Office Action dated 12/15/03 by First Class mail or better to the Commissioner for Patents at P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 12/27/04 Inventor's Signature: _____

Jack V. Smith

the counter for contamination reasons. The nurse may possibly use a paper towel to lay the strip on. Once the results are recorded the nurse will then properly dispose of the test strip and urine specimen and container. Resulting in an inordinate amount of risk, time, and labor.

2. Description of the related art

The present is device that is designed to collect and assay the presence of urinary constituents (analytes of interest) in a biological urine specimen. This specimen could come from humans, animals or other sources submitted for analysis of the analyte of interest. That is to say for example that the present device (invention) is designed to be used for the collection and detection of glucose in the urine specimen or the device is used to collect urine and detect virulent disease causing viruses such as HIV, proteins, viruses, drugs of abuse, drug metabolites, clinical analytes of interest, and therapeutic drugs.

There is no prior **art device** that produces the unexpected results of the present device and the answers to a solution [to] that was never before even recognized that the present art provides. The prior art teaches away from the present art in that it goes in a completely different direction. That is to say that the collection devices of the past for urine were not designed to be used for analysis but strictly collection. For example these devices were strictly designed to collect urine on the ward of a hospital and then be sent to the laboratory for testing. The collection device was designed to collect urine and test however these devices are cumbersome, expensive, and not designed for the specific purpose of testing biological constituents. These some devices are designed to perform analysis of certain constituents but in a cumbersome and messy manner and these devices were not designed to collect urine for any period time and have numerous drawbacks and limitations when related to the advance that the present device brings to the art.

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A thorough search of patents, publications, and research revealed no relative art (i.e., prior art) showing any direct correlation to this novel invention. The search included the USPTO (United States Patent Office) data base with no patents issued for a device designed specifically for biological specimen or other fluid collection and testing that is unique this device. However, the following art will be mentioned to further illustrate the novelty of the present art and the obvious advancement to the current art.

actually has adulteration detection reagents in the reservoir. This is a major problem with regard sample contamination. The complexity of manufacturing and the contamination issues from the adulteration detection reagents to name a few are major drawbacks to these devices. U.S. Pat. No. 5,096,813 to Krumhar is a device designed specifically to for storage and the detection of oxygen and has no relative bearing on the present invention. It is however, a device used for storage and by no means can be compared to the present device which can analyze a specimen at the point of collection, without tilting the cup, or pouring into another device, etc.

While the prior art provides certain devices for the collection of fluids or other types of samples the prior art however suffers from a certain number of drawbacks.

The inflation, insertion, and closure of the prior art devices all require multiple steps and are not simple efficient method to collect and analyzed urine without the risk or contamination, spillage, or other problems. All of the prior art requires tedious and complex methods for use. For instance, the one prior requires that certain the cup be tilted prior to analysis increasing the risk of leakage and contamination as the specimen leaks out of the container. Another device requires the use of a plunger (syringe) for use and yet another requires the use of tilting and a plenum. These are just some, not all, of the limitations of the prior art.

The present device is designed for the analysis of biological specimens on site. That is to say the device can be used for the collection and analysis of the specimen within the container without removal of the specimen and without **having** to adjust the lid of the container, use a plunger, a plenum, or other multiple steps as required by the prior art. The specimen can be analyzed immediately at the point of collection or sent to the lab and tested the next day. The device can be used for long storage of a specimen before testing and / or for immediate analysis. This removes the risk of contamination, mislabeling, chain of custody, and cross over contamination.

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SUMMARY OF THE INVENTION

The present invention is designed to advance the art of urine collection and on site (at the point of collection) analysis past the prior arts drawbacks and provide a collection

collecting the biological fluid and a chamber **32** which provides a means for storing the collected fluid.

The container **12** and assaying means **33** may be formed, or molded, from any suitable material such as plastic, polymers, etc., and may include screw threads **11** at the top of the container **17** formed into the top **17** of the side walls **20** of the container opening **16** and are sized to for accepting the cap **31**. The cap **31** when screwed onto the threads **11** provides a means for sealing the container **12** opening **16**. For typical biological collection to include urinalysis (UA), drug screening, clinical chemistry, etc., the typical container **12** capacity of about 100 to 150 mLs to accommodate split specimen requirement and additional testing.

The assaying means **33** as shown in detail in FIG. **2** towards the bottom **18** of the container includes a spring loaded **24** shaft **13** which is recessed into the wall **28** of the container **12** to prevent accidental activation of the assaying means **33**. The shaft **13** may be blunt or pointed so that it can perforate the opposite inner wall **25** of the chamber **32** and allow the fluid to enter the shaft chamber **22**. The opposite inner wall may be thin to allow easier penetration of the shaft **13** through the inner wall **25** of the chamber **32**. Once the shaft 13 has been depressed (activated) the inner wall **25** [has] becomes perforated and fluid enters the shaft chamber it will come into contact with the assaying means lateral flow material **19** (chromatographic, latex antibody strips, thin layer chromatography, lateral flow material, etc.) and the fluid will start to migrate to the opposite ends of the lateral flow means **19**. During this time the fluid will come into contact with assaying means analyte detecting means **15** (such as dry chemistry test pads for glucose, nitrite, HIV, drugs of abuse, adulterants, etc., or lateral flow strips for drugs of abuse as shown in FIGS. **4** and **5**) and a reaction will take place and a color or other detectable means will be measurable.

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It should be acknowledge that any number of concurrent analyte specific tests may be performed with the device **10** of the present invention. While three assay analyte detecting means **15** strips as shown in FIG. **4** for three strips the device **10** only has to be one assay analyte detecting mean **15** as shown in FIG. **5**. The device **10** may have a wick **29** as shown in FIG **2**. to aid in uptake of fluid from the shaft chamber **22** to the lateral flow material **19** dependent upon the number of assays performed on the device or the

number of later antibody strips **15** as shown in FIG. **4** present if used, etc. The chamber **21** in which the assaying means **33** is located. This chamber is sealed as illustrated to prevent escape of any fluid from within the assaying chamber **21**. Note, the only way for fluid to enter from the shaft chamber **22** to the assaying chamber **21** is via the lateral flow means **19**. Also of note the lateral flow material means **19** can be backed (supported) with a plastic backing or solid plastic or other material means that may extend to the inner wall **26** of the assay means **33**.

This detailed description as provided allows for a marked advance in the art of inflatable packaging. The steps are as follows:

a) collecting the specimen in the cup;
b) placing the lid on the cup and closing;
c) activating the analyzing component of the cup by depressing the activation device;
d) and recording the results of the analysis without the use of a plunger, plenum, or the requirement of tilting the specimen.

The simplicity and novelty of the invention is unmatched in the art. This device could be easily automated and include a magnifying plastic lens that would increase visibility of the assay means results. An automation example would be to have an instrument that depresses the activation device (shaft) then reads the bottom of the container automatically and download the result to a computer. This invention is going to save the clinical diagnostic, drug of abuse testing, and other industries millions of dollars in analysis time, safety prevention and accident control, time (labor), and cost through the novel simplicity of the present invention.

To further explain the

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The invention has been described in detail with particular reference to a preferred embodiment and the operation thereof and it is understood that variations, modifications, and substitution of equivalent means can be effected and still remain within the spirit and scope of the invention. And all such modifications and variations are to be included within the scope of the invention as defined in the appended claims.